6.2 - AMENDMENT OF 2005 ACT: IS THE NEED OF THE HOUR?

The development of intellectual property rights over the years has invariably brought an upsurge in the outlook of nations towards the aspect of societal and cultural growth, this being said with the preliminary assumption that economic growth has been the most affected realm and that it requires a separate spectrum analysis.\textsuperscript{265} IPR is immensely playing significant role as a regime in itself and in the economic growth of a state. The importance of intellectual property protection to develop the scientific and technological capacity of developing countries and benefits derived from the enhanced level of growth and advancement. The so called knowledge economy is wide spread and which includes IPR, and have an incredible and unmatched effect on the overall growth of the society.

The emergence of the GATT and subsequently the WTO has certainly brought in a new paradigm of ideas in the spheres of monopoly rights, particularly in the IPR regime.\textsuperscript{266}

The linkage of intellectual property rights to the world trade regime through the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement),\textsuperscript{267} by members of the newly established world trade

\textsuperscript{265} Kaushik Laik, Role of intellectual property in economic growth, journal of IPR, Vol 10, November 2005, pp465-473

\textsuperscript{266} Ibid

\textsuperscript{267} TRIPs is available at:http://www.wto.org/english
organization (WTO), effectively introduced new millennium standards of intellectual property protection for WTO members.

India’s accession to World Trade Organization (“WTO”) in 1995 is marked as an important phase in the development of India’s patent laws. Prior to India’s accession to the WTO, the 1970 Act, had been undisturbed for a period of 29 years. Beginning in 1999, a series of amendments were enacted in order to bring the 1970 Act into compliance with TRIPS. The first amendment came in 1999, with retrospective effect from January 1, 1995, to provide interim protection to inventions relating to pharmaceutical products by accepting mail box applications which would retain the priority of such inventions until the “mail box” opened in 2005 with the official introduction of product patents. 268

The amendment also provided for the grant of exclusive marketing rights for such products. 269 The Act was again amended in 2002 to incorporate the

268See TRIPS, Art. 70.8 which states: “Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with the obligations under Article 27, that member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
(b) apply to these applications, as of date of the application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria are being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those applications that meet the criteria for protection referred to in sub paragraph (b).

269See ibid. Article 70.9: “Where a product is subject of a patent application in a Member in accordance with paragraph 8 (a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, above for a period of five years after obtaining market approval in That Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that subsequent to the entry into force of the WTO agreement, a patent
second set of TRIPS obligations *i.e.* extension of term of patents to 20 years, reversal of burden of proof, etc. 270 and in 2005 for granting product patents in all fields of technology including chemicals, food, drugs and agrochemicals, etc. 271 (As stated earlier, the Patents Act 1970 has been amended by the Patents (Amendment) Act 1999 to fulfil the TRIPS obligations during the transitional period. The amendments under this Act mainly provided for:

1) Establishing of 'Mail Box' facility as from 1.1.1995 to receive product patent applications in the field of pharmaceuticals and agro-chemicals. This amendment was necessitated from 1.1.1995, as India did not provide product patent protection in two areas.

2) The other amendment established 'Exclusive Marketing Rights' provision in respect of patent applications filed for patent protection in pharmaceuticals and agro-chemical products in the 'Mail Box' referred to at (1) above.

The Patents (Second Amendment) Act 2002 made comprehensive amendments to various Sections of the Patents Act 1970. These changes in relation to access to pharmaceuticals are broadly as follows:

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270. See TRIPS. Article 65: “Transitional Arrangements: 65.1 Subject to the provisions of paragraph 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.” *Id.* Article 65.2: “A developing country Member is entitled to delay for a further period of four years from the date of application, as Defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.”

271 See *TRIPS* Article 65.4: “To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”
(1) The term of all patents whether product or process, shall be 20 years from the date of filing of patent application.

(2) The 'licensing of right' system which was available earlier has been abolished.

(3) Chapter XVI relating to working of patent, compulsory licenses, licensing of right and revocation of patents have been totally replaced. Compulsory licenses will now be available on any of the following grounds:

   (1) If the reasonable requirement of the public in respect of the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonable/affordable price or that the patent invention is not worked in the territory of India.

   (2) The compulsory license can also be granted if the central government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use. The government will make the notification to that effect, in the official gazette before applications for licenses are entertained.

   (3) Compulsory license will also be granted where the Controller is satisfied on consideration of the application that it is necessary in the circumstances of national emergency or circumstances of extreme urgency or in a case of public non-commercial use, which may arise or is required as the case may be, including public health crisis, relating to HIV/AIDS, tuberculosis, malaria or other epidemics.
(4) As regards the royalty payment, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent.

(5) The license will be issued with a provision that the same is predominantly for supplying in the Indian market. However, in the case of semi-conductor technology, the license granted is to work the invention for public non-commercial use and in the case of license granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be allowed to export the patented product.

(6) The Central Government, in public interest, can direct the Controller to authorize any licensee to import the patented article.

(7) It is also provided that importation of a patented product by any person from a person who is duly authorized by the patentee to sell or distribute the product shall not be considered as an infringement of patent right.

India being a member of WTO has to implement the TRIPS Agreement in totality, and hence the third and final deadline was to introduce product patent protection for pharmaceuticals and agrochemicals by January 1, 2005, to meet this deadline, the Government issued an ordinance dated 26th December, 2004 to amend its patent Act 1970.
This ordinance is replaced by the patents (amendment) Act 2005 which is enforcing in to effect from 1/1/2005. Technically, this amendment was required under TRIPS, introduction of products patents for pharmaceutical inventions and granting product patent in all fields of Technology including chemicals, food, drugs and agrochemicals. In effect of these set of amendments took India into a ‘TRIPS plus regime’.  

**MAJOR CHANGES BROUGHT BY THE AMENDMENT ACT:**

a) Abolition of process patents.

b) Indian manufacturers who were producing the drugs chemicals by using different processes. Interests of such manufacturers were also protected in a limited manner and for their provision to sec. 11A (7) have been incorporated, which provides that such manufacturers can continue to manufacture the product on payment of reasonable royalty to the patent holder.

c) Exclusive marketing rights were abolished.

d) Substantive opposition will be made only after the grant of patent under sec. 25 and sec. 26.

e) Amendments have been made for compulsory licensing and incorporated under sec. 84.

f) The term of patent in case of international application filed under the patent cooperation treaty, shall be 20 years.

g) Permission for export under compulsory licensing in accordance with the provision of sec-84(7)(a)(iii).

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272 Abhishek Dubey ‘TRIPs, patents and the Indian pharmaceuticals industry addressing a new twist in the tail Madras Law Journal civil 8-6-2006 page 21-27

273 V. Gnagadharan on patent (Amendment) Act 2005 & Indian pharmaceuticals, Chemicals And Agro-Industry Excise Law Times vol. 188, 2005 page no 220
There are many other changes which also have taken place to patent Act 1970\textsuperscript{274}.

**INDIAN PHARMACEUTICAL INDUSTRIES**

**India’s Pharmaceutical industry in 2005:**

i. Share of global sales: Value 1%, Volume 8%

ii. Global ranking: 4th in volume, 13th in value

iii. Domestic market: $5.3 billion

iv. Exports: $3.7 billion

v. Imports: $985 million

vi. Bulk drug production: $2.1 billion

vii. Employment: 5 million direct, 24 million indirect.

viii. Capital investment: $1.2 billion

ix. Production costs: Among the lowest in the World, estimated to be 70% less than the West.

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\textsuperscript{274}Intellectual property law by P.Narayanan, Third Edition, Eastern Law House, page no 12
far ensured the supply of affordable drugs spurred widespread protests, both nationally and internationally, to an extent never before witnessed in the annals of intellectual property law making in India. The result is an Act that attempts to balance the competing interests of a variety of stakeholders, including domestic generic medicine producers, the domestic research and development community, foreign multinational pharmaceutical companies, civil society groups concerned with access to medicines and intellectual Property lawyers. Patent Amendment Act 2005 reflects on some of their broader implications. In particular on the introduction of product patents for pharmaceutical inventions and the controversial issue of how this change is likely to impact access to medicines.

Reason behind this strategy of denying product patent protection to pharmaceutical inventions is traceable to the Ayyangar Committee Report, a report that formed the very basis of the Patents Act, 1970. The Committee found that foreigners held between eighty and ninety per cent of Indian patents and that more than ninety per cent of these patents were not even worked in India. The Committee concluded that the system was being exploited by multinationals to achieve monopolistic control over the market, especially in relation to vital industries such as food, chemicals and pharmaceuticals. Medicines were arguably unaffordable to the general public and the drug price index was rising rapidly.

The Committee therefore recommended that certain inventions such as pharmaceutical inventions, food and other chemical inventions be granted only process patent protection. The multinational pharmaceutical industry, on the other hand, argues that such patents are essential to encourage innovation and help the transition of domestic pharmaceutical companies from copycat

276 Discussed in detail in 3rd chapter
generics to innovative R&D companies. They argue that this will serve India’s interests better in the long run and that there are adequate safeguards in the patent regime and other laws to curb a sharp rise in drug prices.

Introduction of product patent would disturb the pharmaceutical industry structure and adversely affect consumer welfare through higher drug prices, with adverse consequences for the health and well-being of citizens, the basis of their view is that the countries such as India where health insurance coverage is so rare, almost all medical expenses are met out of pocket and any change in the demand structure could have significant impact on the poor. The Drugs have become expensive and beyond the reach of the common man due to heavy royalties being charged by the patent holder of such drugs.

6.3- IMPLICATIONS OF THE ACT ON PHARMACEUTICALS IN INDIA

The Indian Pharmaceutical market (IPM) is highly fragmented with about 24,000 players (330 in the organized sector). The top ten companies make up for more than a third of the market. The market is dominated majorly by branded generics which constitutes of nearly 70% to 80% of market. The IPM is valued at Rs 750 billion for the year ending March 2014. The growth in 2014 was subdued at 6% vs 12% in 2013. The growth was impacted as the drug

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277 Patent protection for pharmaceutical products will provide India’s scientists with incentives to discover and develop new life-saving drugs. See PHARMA, PhRMA Welcomes Passage of Patent Bill in India, at http://www.phrma.org/mediaroom/press/releases/23.03.2005.1157.cfm

278 Shamnad Bashir, India’s tryst with TRIPS: The patent (Amendment) Act, 2005, the Indian journal of law and technology, vol1,2005, page 19

279 J.K Bagchi(IAS) Retd ,Intellectual property global and Indian dimension by, Manas Publications
price control order (DPCO) issued notice to bring 348 drugs under price control. Despite this, the Indian pharma market remains one of the fastest growing pharma markets in the world. Currently the IPM is third largest in terms of volume and thirteenth largest in terms of value.  

In India, some of the multinational pharmaceutical companies are focusing on increasing the quantity and quality of FDI in the areas of pharmaceutical R&D and manufacturing. However, in the short run, product patents in India may be less harmful. But, in future, it may be sever because of many off-patented therapeutic equivalents are accessible to the Indian consumer and only around 3 per cent of the drugs marketed in India are patented.

The Indian pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crores (US$7.24bn) by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India have grown at a compounded annual growth rate (CAGR) of 17.8% during the five-year period 2003-04 to 2007-08. The Indian domestic pharmaceutical market size is estimated at US$10.76billion in the year 2008 and is expected to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.

During the pre-TRIPS period on the big pharma industry in India often exhibited a near- complete aversion to technology transfer in respect of bulk drug production. In many cases it had to be incentivized by the Indian government to establish bulk drug production. Studies made on the emerging patterns of technology transfer by the MNCs in India show that the results with respect to technology transfer are least encouraging among the high technology sectors. Before 2005 investments by MNCs in the pharmaceutical sector

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280 Available at www.equitymaster.com

281 Panchal S (patents era: how will pharma firms cope,(2005), retrieved from www.rediff.com

282 Strategy for increasing exports of pharmaceutical products’ Report Task force pharma, ministry of commerce and industry, Dept. of commerce, government of India, page no 08
industries was largely for the expansion of formulation activity. Further after 2005 their preference for the establishment of new operations through the incorporation of wholly owned subsidiaries is also confirmed by the studies. Most analysts are of the view the agreement on TRIPs has not been able to succeed in inducing foreign firms to take up more of overseas R&D in developing countries.

The technology can supersede the availability of strong patent protection. But all studies from the post TRIPS period on the issue of the emerging impact of patent protection on international licensing and overseas R&D many studies were conducted and the link between strong patent regimes and technology transfer is not so easy to test. This is because the aspect of weak capacity of the buyer in a developing country to absorb do seem to show that the costs of technology transfer will increase with the imposition of strong patent systems as they have tended to lead to excessive direct and indirect costs due to restrictive clauses and a decrease in the bargaining power of the technology buyer.283

Besides the domestic market, Indian pharma companies also have a large chunk of their revenues coming from exports. While some are focusing on the generics market in the US, Europe and semi-regulated markets, others are focusing on custom manufacturing for innovator companies. Biopharmaceuticals is also increasingly becoming an area of interest given the complexity in manufacture and limited competition. Welfare through higher drug prices, with adverse consequences for the health and wellbeing of citizens, the basis of their view is that the countries such as India where health insurance coverage is so rare, almost all medical-expenses are met out of

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283DINESH ABROL, Post-TRIPS, Technological Behaviour of the pharmaceutical industry in India, Science, Technology and society9:2(2004), sage publications New Delhi/Thousand okas/ london
pocket and any change in the demand structure could have significant impact on the poor.

After the TRIPS agreement came into force it was argued that there were enough flexibilities in the TRIPS for protecting interest of the generic industries, so as to achieve the goal of providing affordable drugs. The flexibility include freedom to determine the scope of subject matter for product protection\textsuperscript{284}, to determine the grounds on which compulsory license could be issued\textsuperscript{285}, in identifying excepting to patent\textsuperscript{286} providing provisions for parallel import\textsuperscript{287}, and protection of test data\textsuperscript{288}, etc.

Countries adopted various approaches to implement the obligations and tried to protect public interest of providing access to affordable drugs. But it was realized that it is difficult to provide access to new drugs in many cases.

Under objectives of the TRPS agreement\textsuperscript{289} clearly lays down that the protection and enforcement of IPR rights are subject to social and economic welfare. They are intended to benefit society as a whole and do not aim at the mere protection of private rights. Art. 8 provide that members may adopt measures to protect health, among other over-reaching public policy objective such as nutrition and socio-economic and technological development.

While the intellectual property practices including patent laws and practices are undergoing major changes globally, the Indian patent laws are consolidated, more specifically in the field of pharmaceuticals. Pharmaceutical firms operating in India will give up to the competitive pressure imminent in

\textsuperscript{284} Art 27 of the TRIPS used the standards of novelty, inventive step and capable of industrial application to identify inventions for grant of patents.
\textsuperscript{285} Art 31 of the TRIPS gives the freedom
\textsuperscript{286} Art 30 identifies three steps to determine the limitation and exceptions to patent
\textsuperscript{287} Art 6 of the TRIP's makes it clear that for the purposes of dispute settlement under this agreement subject to the provisions of art 364 nothing in this agreement shall be used to address the issue of exhaustion of IPR
\textsuperscript{288} Article 39-3 deals with this
\textsuperscript{289} Art. 7 of TRIPS
the product patent era. Stimulating the desired research and development actively among the Indian pharmaceuticals sector will not only strengthen the industrial base but also fuel research about certain diseases. India should adopt a policy of legislative modalities to encourage industrial activity rather than controlling them.

While at the macro level, the government should support and provide facilities for corporation whether in the national or multinational sector should develop their own strengths. It also supports for huge investment from MNCs for growth of these MNCs.

It’s moreover, significant number of firms who had already geared their production and policies in sight of the 2005 changeover will become global players, in the process of creating jobs and wealth, generating significant tax revenue to the government.

Indian Parma companies are going to face stiff competition from the global companies. Indian companies can go either for collaboration or concentrate on producing and marketing generic drugs. This futuristic conclusion is based on the realistic assumption regarding poor research and market penetration strategies by the Indian companies.

The Strengthening DPCO and bringing bio pharmaceuticals within its purview. The Indian bio pharmaceuticals alone have the potential to reach us $2 billion marked size by 2019.

The Indian pharmaceutical industry is poised for growth and its support by its quality human resources with the knowledge and technology base, coupled with the institutional infrastructure, which has been developed over the past few decades. Profitable value realization by the Indian pharmaceutical industry would only be possible if an enabling national environment is created that is conducive to innovation.
The focus under the R&D effort is to encourage development of new molecules. A provision of Rs. 150 crore has been made under the Pharmaceutical Research & Development Support Fund. A Drug Development Promotion Board under the Department of Science & Technology has also been set up for the utilization of this fund. Feasibility of setting up a Mega Chemical Industrial Estate in the country with world class infrastructure facilities is also being studied. For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India.

The advocates of strict patent regime generally argued that product patent would lead to an increase in the international technology transfer to India by encouraging foreign firms to introduce their new products and relocating their R&D units in to the country because of its cheap personnel costs. The trends in R&D intensity, however, appear to be not supportive of this view. Foreign firms, given their captive access to the laboratories of their patents, are incurring minimal R&D expenditure in the nature of local adaption of their product in the country. This is in accordance with the trend in R&D activity of Multi National Enterprises to be concentrated in the home country because of the economies, and a need to protect firm-specific technology.

The country had bitter experience with the Patent & Designs Act, 1911 where a strong patent regime led foreign firms to merely engage in trading activities by processing imported bulk drugs in to formulations and virtually holding back indigenous efforts towards technological self-sufficiency. Empirical studies on their relationship between patent protection and location of R&D activity by MNCs fail to detect any significant correlation in the case of
developing countries. Therefore, the low R&D intensity is going to be changed substantially after the product patent regime comes into force. Given their monopoly status enjoyed under TRIPs and also provision that imports of the product is akin to local production, the hope on foreign firms as a source of R&D activity may be unrealistic.

It is encouraging to find that R&D intensity of the industry has risen substantially in the latter part of the nineties. However, it is very low compared to existing international level of 10-15 percent of sales. The fact that only one third of sample firms were incurring R&D expenses in the industry needs attention. Further, most of the research efforts are confined to process improvements and, to a limited extent, to research on drug delivery system. Barring a few firms, industry has not yet made progress in channeling research activity into basic research where the goal is to invent new drugs. The resource constraints appear to explain this inability of private sector firms to meet the huge cost entailed in developing a new drug. This is clear from the fact that from Independence to 2001, only 14 new drugs have been developed in the country out of which 11 have come from CSIR, a public funded research institution.

The Research & Developing activity in Indian pharmaceutical industry has increased substantially in the latter half of the nineties; both in absolute amount in rupees spent and have a proportion of the total turnover. The estimated R&D expenditure by the sample firms has risen from mere Rs 8 crores in 1990 to an impressive figure of Rs 515 crore in 2001. The trend in R&D intensity indicates that the sample firms have spent around 2.2 percent of their sales in 2001 as compared to 0.2 percent in 1990. In terms of R&D intensity, the performance of foreign firms is, however, observed to be contrary to the expectation, compared to domestic firms. The observed R&D intensity of domestic firms, 2.6 percent, is three and half times higher than that of foreign firms, which is low at 0.74 percent. The R&D intensity curve of the
domestic firms is lying continuously above the sample average since 1994 and has been more or less rising, while that of foreign firms is continually lying below the sample average after 1994 and appear to be declining since 1997.

The number of firms is unevenly distributed across different classes with a strong concentration in the lower end. There are 139 firms in the industry who did not undertake any R&D activity (0.0-0.0 size) and another 47 firms who engaged in R&D but it amounted to less than 1% of their total sales (0.0-1.0 size). Only in case of 16 firms the observed R&D intensity was found to be respectable at 3.0 percent and above. Therefore, the pattern of R&D activity in Indian pharmaceutical industry reveals that majority of firms do not engage in innovative activities and the majority of firms do not engage in innovative activities and majority of those engaged spent very small proportion of their sales.

A list of twenty firms, with largest R&D expenses incurred during the period 1999-2000. Ranbaxy Laboratories Ltd., spent around Rs 55 crore in R&D activity and ranks at the top. It is one of the few research based domestic pharmaceutical companies driving the competitiveness of the industry in international market with subsidiaries in more than 20 countries across the globe. The company has a strong presence in the anti-infective segment with 12 brands in the top 250 in the domestic market.

The Indian company that has ranked second in terms of R&D expenses is Wockardt Ltd., it has very strong presence in antibiotics and analgesics. Even though, the company stood second in absolute amount of R&D expenses in relation to sales. There are only two foreign firms, namely Novartis India Ltd. And GlaxoSmithKline Pharmaceuticals Ltd, which make in to the list by
virtue of their absolute amount of R&D expenditure. It is important to note that these two foreign firms spent substantial amount on R&D in absolute terms; but it is in fact very nominal in terms of R&D intensity. These two firms stood last in the rank based on R&D intensity.²⁹⁰

India’s pharmaceutical industry today stands among the technologically most vibrant segments of Indian manufacturing. It is well understood in the literature that the level of growth and technological development exhibited by the industry is a success of strategic policy interventions consciously undertaken since the 1960’s with the specific objects of self-sufficiency in drugs technology and accessibility of quality of drugs at reasonable prices.

The pharmaceutical industry is a research and development intensive industry. Therefore, a continuous flow of R&D efforts is essential for the development of pharmaceutical industry. Against the backdrop of the recent policy reforms, the most important question is, how has the indigenous technological activity of the industry been affected by the new policy regime. It will also analyze the role of several firm-specific characteristics like firm size, age, knowledge acquisition from abroad, export orientation, outward investment, multinational affiliations, etc., which literature on R&D has identified as important determinants of R&D behaviour at the firm level. The main purpose of such a quantitative analysis is to derive some strategic policy options that can help to strengthen the technological life-blood of the industry to maintain its competitiveness in a liberalizing regime coupled with product patent system.

The primary mechanism that justifies investment in R&D in knowledge based industry is the protection that patents and other intellectual property rights provide to generate intellectual property. Thus, sustained competitive

advantage will depend on the ability of these organizations to create, manage and market value added intellectual assets to derive the advantage of being first in the market.²⁹¹

It is when the major global players are looking for destinations for off-shoring activities like manufacturing and a part or the entire R&D process, India’s inherent strengths makes it a lucrative destination for them. The mutual need has led to emerge of Networked Pharma Model through which the major players in the Indian pharmaceutical industry are all set to leverage its strength and exploit the opportunities provided by the emerging business environment. Many pharmaceutical firms are adopting new internationalization strategies for meeting such challenges and achieving their goal for global growth. They are strengthening their geographical presence by starting their own subsidiaries and affiliates in different strategic overseas markets. They are aggressively acquiring overseas business enterprises, brands and research facilities, strategic alliances with and contract manufacturing, R&D and marketing for pharmaceutical companies from developed countries are also being employed by Indian pharmaceutical companies.

A new concept that is gaining momentum in the pharmaceutical industry is contract research, contract manufacturing & contract clinical trials. Given the low cost high quality advantages, Indian companies are poised to benefit from contract research business on behalf of MNCs. As regards contract manufacturing, large MNC pharmaceutical companies are finding it profitable to outsource their production requirements to India. One of the positive developments after 2005 is that there is a structural change in the industry, which has encouraged innovation and greater investment in R&D. While there

would not be any impact in the short term. In long term this will lead to strengthening and consolidation of the industry. Companies have been increasingly stepping up their R&D expenditure in a bid to be recognized as research and discovery oriented companies in the global arena from the long term perspective.

The Indian government can take several policy measures for enhancing the nation’s competitiveness in the pharmaceutical sectors. A fragmented domestic market marked by a lower degree of domestic competition is not conducive for global competitiveness. Hence, policy measures are needed to encourage mergers and acquisitions among domestic firms to offset the scale disadvantage and to overcome the trap of low R&D intensity.

Increase in average firm size through M&A until the concentration index of the industry rises significantly, may result in improving India’s competitive advantages in the pharmaceutical sector. Government policies that encourage overseas acquisitions by the Indian companies for brands, technology and market access can also be important for strengthening firm’s technological capabilities. Government has taken the following initiatives to support & encourage Indian pharmaceutical industry in the field of R&D:

1. Tax incentives provided under section 35 clause 2AB of the Income tax act 1961 that allows a weighted deduction of 150% for expenditure relating to in-house research and development extended for five more years until March 2012;

2. Extension of time frame for 150% weighted deduction on R&D to benefit companies like DrReddies & Ran Baxy;
3. Lifesaving vaccines exempt from excise duty;

4. Anti AIDS drugs & Lifesaving are exempt from excise duty which shall encourage companies like Cipla;

5. Clinical trials were provided with service Tax exemption which shall facilitate companies like Nicholas Piramal, focused on contract research and manufacturing business;

6. 150% weighted deduction on R&D provided which shall make contract research more profitable;

7. Tax exemption date for weighted deduction of 150% of in-house R&D facilities of pharmaceutical companies extended;

8. Exemption for 100% deduction of profits for companies carrying on scientific R&D, approved by the CSIR;

9. 100% FDI permitted for the manufacture of drugs & Pharmaceuticals provided the activity does not attract compulsory licensing or involve use of recombinant DNA Technology and specific cell targeted formulation.292

In the recent studies on trade in drugs and pharmaceuticals have generally reported that the Indian pharmaceutical industry is performing extremely well on the export front but the findings in293 show that there has been a decline in the growth rate of exports of intermediates and bulk drugs and formulations, which account for 90.8% of the exports of drugs and pharmaceuticals from India in 2006-07, in the post1999-2000 period, the period during which the monopoly rights of the inventor got protected in India.

293 REJI K Joseph; ‘Estimating India’s Trade in Drugs and Pharmaceuticals’, EPW January 10, 2009 page no
The government should initiate more public R&D programmes that utilize the strengths of the industry. The government has earmarked 150 crores for R&D. This is just not enough and should be augmented to at least 2000 crores.294

The Research & Development (R&D) is a key to the strength of pharmaceutical industry especially in the product patent period. The global pharmaceutical industry spent $30.4 billion (2001) on R&D. The R&D expenditure (as a percentage of turnovers) by the Intellectual Property Industry is low (1.9%) when compared global giants (1016%). With transition into the new regime many Indian companies are mobilizing their resources war chest with an increase in their R&D budget. Government of India (GOI) encouraged the R&D in pharmaceutical companies by extending 10 year tax holiday to this sector. Besides, planning commission has earmarked $34 million towards drug industry R&D promotion fund for the tenth plan295.

The Current only a handful of pharmaceutical firms in India invest in R&D which needs to be improved. The Pharmaceutical Research and Development Committee (1999) has suggested that a mandatory collection and contribution of 1 per cent of MRP of all formulations sold within the country to a fund called pharmaceutical R&D support fund for attracting R&D towards high cost-low-return areas and be administered by the Drug Development Promotion Foundation. The domestic universities and other academic institutions can play the role of research boutiques or contract research organizations (CRO), which can supply the technical know-how and manpower. Units that already have such facilities can also function as a CRO for other firms.

294 Rajanish Kumar Rai, Battling with TRIPS :Emerging firm strategies of Indian pharmaceutical industry post-TRIPS, J OF IPR Vol 13,July 2008 pp301-317
295 Article Source: http://EzineArticles.com/expert=Arvind_Singhatiya
As the patent cliff\textsuperscript{296} is approaching, Indian pharma companies have increased their R&D expenses. The companies are spending more to establish niche product portfolios for the future. Consolidation has increasingly become an important feature of IPM. The recent deals viz; Sun pharma acquiring Ranbaxy, Wyeth and Pfizer merger; Strides selling its injectable arm and so on are the classic cases.

Pfizer, Allergan, GlaxoSmithKline, and many other major pharmaceutical companies will have patents for many drugs expiring within the next three years. Losses in revenue for major pharmaceutical companies will be tremendous, with projections showing the pharmaceutical industry will lose upwards to $127 billion in brand spending by 2016 due to patent expiration and cheaper generics in the market.\textsuperscript{297}

\textbf{FIGURE -1}

![Developed Markets Patent Expiry Exposure and Impact](image)

\textsuperscript{296} A patent cliff is when a firm’s revenues could “fall off a cliff when one or more established products go off-patent, since these products can be replicated and sold at much cheaper prices by competitors, available at http://www.investopedia.com/terms/ppatents-cliff

Figure 1. A projected view of total consumer spending in developed markets until 2016. Dark blue bars indicate spending on generics for the year, while light blue bars show prescription brand spending. Note that over the upcoming years, prescription medicines are estimated to lose $127 billion in potential revenue to generics.298

It is however, over the last three years major pharmaceutical companies have lost tens of billions of dollars to smaller companies for one primary reason: the patent cliff – a series of patent expirations of important prescription drugs. This phenomenon has led to the mass production of generic versions of major drugs by small pharmaceutical companies, causing steep revenue losses for big pharmaceuticals. In the coming years, many prescription drugs that make up many large pharmaceutical companies’ profits, known as blockbuster drugs, are set to expire as intellectual property. This will create a gateway for small companies to flood the market with generics. With hundreds of billions of lost revenue projected, the patent cliff has the opportunity to change the face of the pharmaceutical industry in the consumer perspective, as well as the back-end research, development, and business standpoints of major pharmaceutical companies in the years to come.299

The Government of India has unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. It has reduced approval time for new facilities to boost investments. Further, the government has also put in place mechanisms such as the Drug Price Control Order and the

34 IMS Health
National Pharmaceutical Pricing Authority to address the issue of affordability and availability of medicines.

Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

1. The Andhra Pradesh government will provide necessary infrastructure, incentives and skill up gradation facilities for the pharma industry and the captains of the industry should come forward to invest on a large scale in the state, according to Chief Minister N Chandra Babu Naidu.

2. The Government of India and the pharmaceutical industry will jointly float a trust to promote the brand image of Indian pharma globally and fight malicious campaigns.

3. India plans to set up industrial parks in the pharmaceutical and information technology (IT) sectors in China to strengthen India-China trade and investment ties.

4. The Union Cabinet of India has cleared foreign investment proposal worth US$ 400 million by KKR to acquire stakes in two pharmaceutical companies, Gland Pharma and Gland Celsus Bio Chemicals.\(^\text{300}\)

The pharmaceutical industry in the past did not face any rigours of strong patent systems. The new situation is going to be totally different. A co-relation between the pharmaceutical policy and the patent laws has to be established to the maximum extent so that the industry is able to play its role adequately to facilitate easy access to medicines at competitive prices.\(^\text{301}\)

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\(^{300}\) Indian pharma cos’ R&D spend to increase:ICRA,(http://www.business-standard.com/user/my-page/add-article/item-id) accessed on Dec 22 at 8.30 pm

\(^{301}\) See B.K.,Kealya Review of Patent Legislation in India,Sri-lanka, Indonesia and Thailand, measures to safeguard public Health,SEA-HSD-275, Distribution: General, World Health Organization, Regional Office for South-East Asia, New Delhi,2004
The pharmaceutical industry in India has been identified as one of the most important knowledge-based industries. Since the 1980's the industry has grown rapidly due to enactment of the Patents Act 1970 and announcement of the Drug Policy of 1978. In view of these challenges, a new Pharmaceutical Policy was announced in 2000. The main objectives of this policy are:

(1) Ensuring availability at reasonable prices of quality essential pharmaceuticals of mass consumption.

(2) Strengthening the indigenous capability for cost-effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.

(3) Strengthening the system of quality control of drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.

(4) Encouraging R&D in the pharmaceutical sector compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to canalizing a higher level of investment into R&D in pharmaceuticals in India.

(5) Creating an incentive framework for the pharmaceutical industry to promote new investment and encourage the introduction of new technologies and new drugs.

Drug prices are likely to be influenced by some of the WTO Agreements. For example, WTO negotiations led to the elimination or reduction of import duties on drugs, vaccines and other medical supplies in Member countries. This would help in lowering prices in the importing countries. However, TRIPS Agreement will establish monopolies, which would lead to an increase in drug prices due to more stringent patent
protection. It will also affect the role of the domestic pharmaceutical enterprises in making available drugs at competitive prices.\textsuperscript{302}

The TRIPS Agreement does not contain any exception for health purposes per se, but it does allow measures necessary to protect public health and nutrition, provided they are consistent with other TRIPS provisions (Article 8 - Principles). Doha Declaration on the TRIPS Agreement and Public Health also aims at the concern expressed about the possible implication of the TRIPS Agreement for access to drugs. It does so in a number of ways, such as that 'TRIPS Agreement does not and should not prevent members to protect public health and confirms the right of members to use in full the provisions of TRIPS Agreement for this purpose'. Thus it is now for the Member countries to ensure that their patent laws are framed in such a manner that the objectives of health – care are not hampered in any way.

Worldwide, national governments in the past used their supreme power to evolve their own approach towards their patent system, particularly for drugs and pharmaceuticals. They gradually modified their patent laws related to their stage of development. IPRs laws in these countries were compatible with their developmental objectives. The right to sub serve the public interest in these countries prevailed over the intellectual property right, whereas in the developed countries the welfare objectives are no longer their concern but profiteering is the objective of the TNCs through patent monopolies.\textsuperscript{303} In the background of the flexibility and freedom available to Member countries as stated in its objectives and principles, legislation on patent laws in India, could, ensure that there is proper co-relation of the amended patent system with the National Health Policy, Pharmaceutical Policy and Research and Development Policy so that the objectives of these policies are fully

\textsuperscript{302}See Infra note300
\textsuperscript{303}B.K.Kealya, review of patent legislation in India, sri-lanka, Indonesia and Thailand, measures to safeguard public health, SEA-HSD-275 Distribution: General , World Health Organization, Regional Office for South-East Asia, New Delhi, September 2004
accomplished. The Indian patent Act ensures that the reasonable requirements of the public with respect to availability are taken care of public interest, particularly public health and nutrition is protected and effectively balances intellectual property protection with public health concerns and National Security.

The patenting of drugs would result in price rise (in this case, most of the developing and third world countries) and therefore damage public health. Drugs becoming expensive and beyond the reach of the common man due to heavy royalties being charged by the patent holder of such drugs. Indian industries have to necessarily engage itself in new product development to remain globally competitive. Evidently none of the Indian companies have the financial strength to undertake drug development portfolio. The government is already burdened with its own compulsions.

It is after the TRIPs agreement came into force it was argued that there were enough flexibilities in the TRIPs for protecting interest of the generic industries, so as to achieve the goal of providing affordable drugs. The flexibility include freedom to determine the scope of subject matter for product protection, to determine the grounds on which compulsory license could be issued, in identifying excepting to patent providing provisions for parallel import, and protection of test data, etc.

The industry has been redesigning its business model to fully integrate into the global pharma. The industry began to realize the enormous potential and shifted its focus from manufacturing reverse-engineered copies of patented

304 ibid
305 Art 27 of the TRIPs used the standards of novelty, inventive step and capable of industrial application to identify inventions for grant of patents.
306 Art 31 of the TRIPs gives the freedom
307 Art 30 identifies three steps to determine the limitation and exceptions to patent
308 Art 6 of the TRIPs makes it clear that for the purposes of dispute settlement under this agreement subject to the provisions of Art 364 nothing in this agreement shall be used to address the issue of exhaustion of IPR
309 Article 39 deals with protection of test data
drugs to producing generics for off-patent drugs for exports to lucrative markets such as U.S.\textsuperscript{310}

The Countries adopted various approaches to implement the obligations and tried to protect public interest of providing access to affordable drugs. But it was realized that it is difficult to provide access to new drugs in many cases\textsuperscript{311}, this forced countries to bring health care issues into international attention and demand for clarification and amendment of the TRIPS provision dealing with health care, resulting into Doha Round of Negotiations the Developing countries got major achievement by convincing the world community that public health is a grave issue and TRIPS creates problem in taking effective measure to solve the same.

It is under objectives of the TRIPS agreement\textsuperscript{312} clearly lays down that the protection and enforcement of IPR rights are subject to social and economic welfare. The researcher is in consent with the critical observation as in an article intellectual property & human rights which affirms that “the present IPR regime is not flexible and it contains a (one-size-fits-all approach). According to some critics, the minimum standard of intellectual property protection set by TRIP’s agreement are too high for most of the developing countries there by putting them under tremendous pressure to adopt legislations that is not adapted to their specific needs . It limits to follow their human rights agenda and large segment of society remains deprived of basic human rights. The benefits of scientific progress have not reached to all the segments of society. The main objective of the health policy announced by the government in 2002 is to achieve an acceptable standard of good health for the People. The approach would be to increase access to decentralized public

\textsuperscript{310}Prabodh Malhotra, the impact of TRIPS on innovation and exports: a case study of the pharmaceutical industry in India, Indian Journal of Medical Ethics 2008 apr-jun;jun;5(2)
\textsuperscript{311}TN.S.Gopala Krishnan ,TRIPs Agreement and public health: An overview of international issues, , Journal of IPR vol. 13 sep2008 pp. 397-400
\textsuperscript{312}Art. 7 of TRIPS
health system by establishing new infrastructure in deficient areas, and by upgrading the existing infrastructure. Overriding importance has been given to ensure a more equitable access to health services across the social and geographical expanse of the country. Emphasis will be given to increasing the aggregate public health investment through a substantially increased contribution by the Central government. It is expected that this initiative will strengthen the capacity of the public health administration at the state level to render effective service delivery. The contribution of the private sector in providing health services would be significantly enhanced, particularly for the population group which can afford to pay.

In the post-independence period, statutory control on drugs was first introduced in 1962. However, owing to criticism from the industry, the Government made changes in the Drug Price Control Order. Subsequently, the Government identified a list of 18 essential drugs and referred them to the Tariff Commission. The Tariff Commission was asked to go into the various aspects of the cost structure of these essential lifesaving drugs and asked it to recommend reasonable prices. Realizing the importance of checking the prices of drugs from escalating to phenomenal heights, the Drug Price Control Order, the first of its kind with a thorough analysis, was introduced by the Government of India in 1970. The Price Control Order was meant to keep the prices of drugs at affordable limits to the consumers and at the same time ensure that producers received reasonable returns. The Order captured 347 bulk drugs under its net, which were placed in various categories. The minimum percentage of profit margin was granted to different categories and producers were allowed to charge a maximum amount of post-manufacturing expenses.
The other vital feature of this Order relates to the stipulation of minimum ratio of bulk drugs to formulations. A broad-based drug policy was formulated based on Hathi Committee Report of 1975. Based on Hathi Committee’s recommendations, the Government announced Drug (Price Control) Policy, 1979. Some of the key objectives of the Policy were:

i. To ensure adequate availability of drugs

ii. To provide drugs at affordable prices

iii. To ensure the quality of drugs and check medicines from being adulterate.

iv. To achieve self-sufficiency in production and self-reliance in drug technology.

Drug Regulation in India

In India, the drug regulatory system has been poor and neglected over the years, although much has been written and recommended by various committees. Poor enforcement mechanisms and multiple interpretations of the Drugs and Cosmetics Act 1940 have made regulation in this sector an unviable proposition (GOI 2003). In some States such as West Bengal, Rajasthan and Punjab, there is no testing laboratory. Assuming a norm of one inspector for every 50 manufacturing units and one inspector for 200 sales units, the gap between the required normal and the actual number of available drug inspectors is woefully inadequate.

313Access to essential Drugs and Medicine, section III.NCMH Background papers( Delivery of healthcare services in India) National commission on Macroeconomics and Health, Ministry of Health and family Welfare,Aug 2005, page no,
Given the currently available figure of 935 drug inspectors, one inspector serves around 320 wholesale and retail units instead of a norm of 200. This could be the reason why the number of spurious and substandard drugs detected was relatively less. With adequate manpower and infrastructure, inspection of manufacturing and sales premises alongside a strong surveillance mechanism relating to the movement of spurious/counterfeit drugs could be carried out and unearthed more rigorously.

As far as the manufacturing units are concerned, the Government of India noted that roughly around 5900 units require intense surveillance/inspection and not all the 20,000 units (Mashelkar Committee Report 2003). Further, the Committee noted that the 1333 bulk drug units, 4354 formulation units, 134 large volumeparenterals (LVP) and vaccine manufacturing units-accounting for 5877 units-are the ones that require intense inspection. The other major categories are cosmetics, loan licenses, blood banks, etc. According to the Mashelkar Committee, around 120 drugs inspectors are needed to monitor about 5877 units and another 100 inspectors are required for the remaining categories. The Mashelkar Committee proposes a Central Drug Administration (CDA) to be set up under the Ministry of Health and Family Welfare with autonomous status. The Committee recommended the setting-up of the CDA by the end of 2004 and State-level regulatory systems be strengthened accordingly.

01. Review C & C1 licenses under the Drugs and Cosmetics Rules issued against manufacturing and distribution (wholesalers & retailers) to keep abreast with recent developments in the drugs sector.

02. Review the Schedule H drug which provides a list of prescription drugs.
03. Comprehensively review Schedule K of OTC (over-the-counter) drugs.

04. Curb inter-State movement of spurious drugs, tone up the existing communication network and freely exchange information between States.

As far as the health food/therapeutic foods/dietary supplements are concerned, regulation relating to their quality and safety is needed as the demand for such products is increasing, and producers/sellers are indulging in exaggerated claims. These products should be brought under the purview of the relevant food law. However, any product that has ‘distinct medicinal claims’ would be qualified as a drug and not food products.

There is a growing market for Indian Systems of Medicine (ISM), herbal products and drugs of natural origin. Concern has been voiced over their efficacy and quality. Efforts need to be made to update the requirements for licensing such products. Since for many such products long-term safety data are not available on their usage, additional safety data need to be obtained.

The other area of concern is uncontrolled growth of medical devices and equipment. Other observations and recommendations made by the Committee\textsuperscript{314} are as follows:

a. Strengthen the infrastructure and manpower relating to the monitoring/surveillance/inspection mechanism, both at Central and State level.

b. Information received by the Mashelkar Committee reveals that only 17 out of 31 States has a drug-testing facility; of 17 only 7 appear to be ‘reasonably equipped/staffed’.

\textsuperscript{314}MashelkarcommitteeReport on “a comprehensive examination of drug regulatory issues in India, problem of superiousdrugs,” ministry of health and family welfare govt of India2003
c. Measures are needed to tone up the Drugs and Cosmetics Act 1940, providing it with more powers (penalties) against manufacturers and distributors.

An intellectual property regime necessarily sets up a monopoly which limits the supply of alternatives for a given chemical entity to a single firm. Despite the existence of several substitutes (either because of other older molecules or due to the absence of product patents), lack of information and reliance on the physician to prescribe a drug lead to the persistence of high price for well-established pharmaceutical products.

The pharmaceutical industry is world’s one of the high research-intensive industries, generating enormous contributions to healthcare. Patents are granted to create strong incentives for investment in pharmaceutical research and development but that result in monopoly privileges by creating scarcity. This monopoly grant arouses public concern over high prices and the introduction of products of uncertain efficacy or safety.

The pharmaceutical industry has a distinguishing characteristic of imperfect information on the quality of the product. The pharmaceutical products are often obtained on prescription from a physician. Thus, the consumer is not the decision maker. This has serious implications for prices of the pharmaceutical products as the physician is not as sensitive to prices as the direct consumer would be. The presence of monopoly power results in prices that commonly exceed drug production costs by substantial margin.
6.3 IMPACT ON DRUGS:

The domestic pharmaceuticals industry in India meets almost 95% of the country’s needs. A substantial portion of the production is exported. Cost of production of bulk drugs in India is about 60% less than that in the west. India has substantial cost advantage also in pharmaceutical research and development, and clinical trials. Implementing the process of a new drug discovery in India will cost only 5 to 10% of the cost in the west. For clinical trials, similarly, the cost in India is only a small fraction of the costs in the west. The Indian pharmaceuticals industry accounts for the second largest number of abbreviated new drug applications. India is the world leader in drug master files applications with the U.S. Food Drug Administrator (USFDA). There are 75 USFDA approved manufacturing facilities in India, more than in any other countries outside the U.S. all these signify the high level of technical competence achieved by the Indian industry.

Some of the biggest challenges faced by the pharmaceutical industry in India is whether it will adversely affect consumers. The domestic pharmaceutical industry has, however been able to meet the challenges of the new regime and exploit it to its advantage with appropriate firm strategies. Indian pharmaceutical firms have adopted to meet the challenges of the new patent regime. Industry is adopting a mix of competitive and collaborative business and R&D strategies in the emerging business environment. Industry is witnessing a transition phase, and is undergoing consolidation and

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315 FICCI Report 2005
317 Rai R, Effect of the TRIPs-Mandated intellectual property rights on Foreign Direct Investment in Developing countries: A Case Study Of Indian Pharmaceuticals, JOWIP 5-6 (2009)
restructuring.\textsuperscript{318} To meet the product patent challenge, many Indian pharmaceutical firms are adopting a multistage strategy of moving up the product value chain and increasing exports to regulated markets.\textsuperscript{319} Leading companies have moved away from a reliance on the domestic market to the development of new drugs, exports to regulated markets,

Till 2005 drugs and their formulations in India were sold as generic (off-patented) drugs. As limited time has elapsed since the implementation of product patent regime, there are very few patented drugs which have entered the market. The patent regime shift in Indian pharmaceuticals would change the market structure from Oligopolistic market structure to a pure monopoly in the drugs market. The monolithic tendencies which are associated with patented drugs are of a much larger magnitude as compared to those with the off-patented drugs.

The main concern of introduction of patents is higher prices and displacement of domestic firms which are at a disadvantage in terms of developing innovative drugs. The prices of drugs, whether patented or non-patented, are a function manufacturing costs, imports, presence of large firms, therapeutic advantage of the drug and presence of alternative drugs. Thus in India, despite patent free regime in 2005 wide variations were observed in the prices of different brands of drugs along with a variation in the average prices of different molecules in the same therapeutic segment.

FY14/CY13 was challenging on the domestic front. The companies witnessed sluggish growth on the back of pricing policy. The companies faced strikes

\textsuperscript{318} ibid
\textsuperscript{319} Grace, The Effect of Changing Intellectual property on pharmaceutical industry, prospects in India and china, DFID, Health systems resources center, London,2004
from the wholesales on margin issues due to reduction in prices of overall drugs.

MNC pharma companies continued to witness subdued growth during FY14/CY13. It is important to note, the growth of the MNC players was below the domestic pharma companies. The pricing policy had a negative impact on the company's revenues. Over and above, these companies were also impacted by the increasing competition, drug launches by other companies before patent expiry, through compulsory licensing and patent infringements. Only couple of companies exhibited better growth. The margins of these companies remained subdued due to increasing expenses and slower top line growth. The industry continued to face challenges on the regulatory front. During the year, there were few Indian companies that faced issues from the USFDA, as they lacked good manufacturing practices (GMP). Because of this, there were instances of import alerts being issued, drug recalls, warning letters and so on. The regulators have become more stringent now and have also been conducting surprise checks.

Prospects of Indian pharmaceutical industries.

- The IPM size is expected to grow to US$ 85 billion by 2020. The growth in Indian domestic market will be boosted by increasing consumer spending, rapid urbanization, and increasing healthcare insurance and so on.

- The life style segments such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers will continue to be lucrative and fast growing owing to increased urbanization and change in lifestyle patterns. Going forward, better growth in domestic sales will depend on the ability of
companies to align their product portfolio towards these chronic therapies as these diseases are on the rise.

In various global markets, the government has been taking several cost effective measures in order to bring down healthcare expenses. Thus, governments are focusing on speedy introduction of generic drugs into the market. This too will benefit Indian pharma companies. However, despite this huge promise, intense competition and consequent price erosion would continue to remain a cause for concern. Over and above this, following GMP will be an important criterion for companies in order to grow in the global markets.

For the US market, Indian companies are developing niche portfolios in various segments. High margin injectable, dermatology, respiratory, bio generics, complex generics etc. have become an area of interest. Most of the Indian pharma companies have been working on these niche drugs in order to optimize growth and margins. Thus, post patent cliff, the companies which have developed their product basket in the niche category will be ahead in the curve. Moreover, generic penetration in the US is expected to peak out at 86-87% over the next couple of years from 83% currently.  

The domestic market will also see a significant growth in sales on the back of increasing affluence, changing lifestyles resulting in higher incidence of lifestyle-related diseases, increasing government expenditure on healthcare through schemes like the Central Government Health Scheme (CGHS), National Programme for Healthcare of the Elderly (NPHCE), RashtriyaArogyaNidhi (RAN) and Janani Suraksha Yojana (JSY) in the next three years, according to Care analysis.

320 http://www.equitymaster.com/research-it/sector-info/pharma/pharmaceutical-sector-analyst-, accessed on 22nd December, at 8.30pm report
The rise of pharmaceutical outsourcing and investments by multinational companies (MNCs), allied with the country's growing economy, committed health insurance segment and improved healthcare facilities, is expected to drive the market's growth.\textsuperscript{321}

Indian firms developing new chemical-entities and receiving stronger protection are an indication of the drug candidates emerging from Indian pharmaceutical manufactures. NWCs have become more comfortable in giving assignments to India due to the security afforded by product patents. This is the aspect of mergers takeovers and acquisitions which world would be addressed by the competition law.

The pharmaceutical industry is the world's second-largest by volume and is likely to lead the manufacturing sector of India. India's bio-tech industry clocked a 17 percent growth with revenues of Rs.137 billion ($3 billion) in the 2009-10 financial year over the previous fiscal. Bio-pharma was the biggest contributor generating 60 percent of the industry's growth at Rs.8,829 crore, followed by bio-services at Rs.2,639 crore and bio-agri at Rs.1,936 crore.

During year 2009-10, Pharma was among the few sectors that managed to expand its revenues despite global recession and financial crises. Strong domestic demand, growing preference for generics worldwide and favourable rupee-dollar exchange rate helped the Indian Pharmaceutical sector. Aggregate income of the drugs and pharmaceuticals companies for the first two quarters of the current year grew by 13 per cent and 7.8 percent respectively as compared to previous year. As per Centre for Monitoring Indian Economy (CMIE), the estimated growth in aggregate income for the next two quarters is 9.5 per cent and 10.2 percent respectively.

The next major concern was the status of patented drugs that are exported to various third world countries. Indian drugs are the principal source of cheap

\textsuperscript{321} ibid
drugs for poor developing countries specially the African nations. 66.7% of Indians exports go to the developing countries. This can be threat for export accounts to counter this problem a new section 92A introduced by the ordinance, which allowed for the manufacture and export a patented drugs to countries having insufficient or no manufacturing capacity to address public health.322.

It is at the same time it must be accepted that product patents have benefited other segments of the Indian pharmaceutical industry. It is important not to overlook the international competitiveness of Indian firms in innovative research, which will benefit Indian public health in the long run.

Indian firms developing new chemical-entities and receiving stronger protection are an indication of the drug candidates emerging from Indian pharmaceutical manufactures. NWCs have become more comfortable in giving assignments to India due to the security afforded by product patents. This is the aspect of mergers takeovers and acquisitions which world would be addressed by the competition law.

Task force was constituted in July 2006 to recommend measures for increasing exports of pharmaceutical products.323

I. To examine the problems being faced by the exporters of pharmaceutical products in consultation with the stakeholders and to prepare short-term, medium-term and long-term Action Plans.

II. To review the progress of export of pharmaceutical products and suggest measures of achieving the growth targets.

322 See supra note 273
323 See supra note , 282
III. To act as ‘Think Tank’ and make appropriate policy recommendations for boosting exports and generating more employment in the sector.

IV. To consult the trade and industry and identify policy and procedural bottlenecks and suggest ways to eliminate them.

**International Co-operation/Export Promotion**

An important focus area for the Department of Pharmaceuticals is of promotion of Indian pharma exports. The Department participated in the following International Cooperation events during 2009-10:-

I. The fourth meeting of the India-EU Joint Working Group on Pharmaceuticals and Biotechnology was held in the month (September, 2009 at New Delhi under the Co- chairmanship of Shri ArunJha, Joint Secretary (Pharma).

II. Participation in the BIO 2009, held in May, 2009 in USA.

III. Participation in the India-USA HTCG, held in May, 2009 on the margins of BIO 2009.

IV. Organization of Brand India -Indian Pharma Expo in Myanmar from 12-14 June, 2009.

V. Participation in the 45th Annual Meeting of the DIA, held in June 2009 in San Diego, USA.

VI. Organization of India Pharma Summit 2009, on 30th September 2009 in Mumbai and celebration of India Day on 1st December, 2009 and CPhl 2009, held from 1st to 3rd December, 2009.
VII. Participation in the US-India Bio Pharma and Healthcare Summit which was held in Boston on 14-15 May, 2009.

VIII. Visit of Nigerian delegation led by DG, National Agency for Food & Drug Administration & Control to India in connection with wrong labeling of generic drugs as being of Indian origin even while not being actually made in India.

Department of Pharmaceuticals also provided financial assistance for following activities, for promotion and development of the sector:

a) Publishing of advertisement in Kazakh journal "Ghazab Hindustan" for promotion of Indian Pharma products in Kazakhstan.

b) Conducting of Pre-feasibility study for development of a Greenfield Project for Medical Devices Cluster in Gujarat and a Brownfield Project for Bulk Drugs Cluster in Andhra Pradesh.

c) Presentation of Patent Awards on the eve of Indo-Africa Pharma Business Meet.

d) Preparation of Film on Pharma Industry in India.

e) The major concern was the need to facilitate access to essential medicines at affordable cost to the large sections of the population. Intellectual property protection for inventions relating to health case was one of the most debated areas in the international negotiations for IPR protection in the last three decades. Equally important was the demand to ensure adequate reward through patent system to the pharmaceutical companies mainly located in the developed nations.
who make considerable investment for the invention, production and marketing of essential drugs\textsuperscript{324}.

It is an interesting feature of the amendment which takes care of the interests of the generic industry is that after a patent has been granted for a product in the mailbox, no infringement Act can be initiated against a generic manufacturer who can continue to produce that product subject to certain conditions. The amendment states that a currently marketed generic product can continue to be commercialized once it provided those domestic generic manufacturers pay reasonable royalties to the patent holders. Because of these provisions some of the generic producers can continue with the production, the amendment is in favor of generic producers\textsuperscript{325} Indian pharmaceuticals to achieve their aim are following the development of new drugs. Absence of any large scale Research and Development investments in both public and private sectors and continued government apathy to provide long term promotional schemes\textsuperscript{326}

It is for the first time in many decades the Indian pharmaceutical industry felt threatened in their home pitch, while a few visionary corporate like Dr. Reddy’s started initiating actions to face the challenges of product patent regime for early 1990’s, by setting up a Drug Discovery Programme\textsuperscript{327}. While reasonable good numbers of Indian pharmaceutical corporations, have set up research facilities of global standard and have initiated research

\textsuperscript{324} Press information bureau by govt of India

\textsuperscript{325} N.S. Gopala Krishnan, TRIPs Agreement and Public Health: An overview of international issues, Journal of IPR vol. 13 sep2008 pp. 397-400

\textsuperscript{326} N. Lalitha., Doha Declaration and Public Health issues, Journal of IPR, Vol 13, Sep 2008, pp.401-413

programmes for New Drug Delivery Systems and also cases of Drug discovery programme, by the overseas pharmaceutical corporations.\textsuperscript{328}

1) A new breed of service providers with specialized skills across different research verticals is emerging very fast. These players offer high end, high quality, cost effective services across various research segments with outstanding and off shoring has become common pharmaceutical firms across the globe are increasingly showing interest in these services providers and has transferred their discovery research to them. Hence, there is a substantial rise in the R&D budget of companies has been noticed over the years towards this endeavour. With the product patent regime in operation, this offers a great opportunity for Indian drug research companies who can now play a vital role in creating IP for big multinational due to India advantage.\textsuperscript{329}

2) Union government has come up with a scheme involving a gold standard certification. This would entitle pharma companies to claim a 200% maximum allowable post manufacturing expense (MAPE) component while fixing the product prices in respect of 354 lifesaving drugs proposed to be brought under the control regime.\textsuperscript{330}

3) Production of off-patent drugs will emerge as one of the important manufacturing activities of Indian pharmaceutical firms.

\textsuperscript{328}Gopakumar G Nair., Impact of TRIPs on Indian pharmaceuticals industry, Journal. of IPR vol. 13 Sep 2008 page no. 432-441

\textsuperscript{329} Supra note 292 page 439

\textsuperscript{330} See details supra note 291 page 419
4) Furthermore, off patent (generic) drugs made by Indian firms are going to meet most of the domestic demand\textsuperscript{331}.

Marketing of important drugs many Indian firms are interested in entering into long term arrangements with global business. Introduction of product patent would disturb the pharmaceutical industry structure and adversely affect consumer. Worldwide, drug prices are subject to controls and regulations. A host of policy instruments are exercised to rein in drug prices from increasing to unreasonable levels. Such controls take the following forms, either singly or in combination with more than one instrument, cap on mark-ups, fixed margins to wholesalers/pharmacists, price freezes, reimbursements, reference pricing, contributions to insurance premium, patient co-payments, generic substitution, ceiling on promotional expenditure, differential value added tax on drugs etc. Fixing margins on the profit of pharmaceutical companies.\textsuperscript{332} It is also forms part of drug price control/management. The starting point for a consideration of the operational aspects of intellectual property system with regard to access to drugs is that access to essential drugs is a Human Right\textsuperscript{333}.

Article 21 of the Indian constitution provides Right to life and it shelters various rights. It includes Right to Health, which implies, “The Right to a variety of facilities and conditions necessary for the realization of the highest attainable standard of health”. The Right to health is one of the economic, social and cultural human right that requires affirmative government action to create better condition for people rather than just governmental restraint vis-a-vis citizens. The first expression of this right is an international legal instrument came in the constitution of W.H.O in 1946\textsuperscript{334}. Since India is a founding member of UNO, UDHR & ICESR the Art. 25 of UDHR\textsuperscript{335} and Art

\textsuperscript{331} Pharmaceuticals & India http: // www.Cuts.international.org 1997 8. htm# RIPS,% 20 pharmaceuticals %20  
\textsuperscript{332} ibid  
\textsuperscript{333} KumarAvinash, “ Human rights to health” satyam law international, 2007 at 21  
\textsuperscript{334} International Covenant on Economic, Social and Cultural Rights  
\textsuperscript{335} Universal Declaration of Human Rights
12 of ICESCR, World Health Declaration (1998) adopted by the World Health Assembly speaks about Right to Health. Hence, it is the responsibility of all the members’ countries to provide right to health to all its citizens.

The World Health Organization’s (WHO) drug policy clearly aims at providing a health for all and accessibility of primary healthcare and medicine to all the human beings of the world, irrespective of colour, creed and economic status\textsuperscript{336}.

6.5- AVAILABILITY AND AFFORDABILITY: A MEETING POINT?

The World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. Public health refers to all organized measures to prevent disease, promote health, and prolong life of the population as a whole.

Health is humankind's most basic and essential need. It is the most precious possession, next perhaps only to life itself. Good health is important for a variety of reasons. Health and the linkages between health policies and trade related issues are the major concern of mankind especially for the vast masses living in developing and least developed countries. Public health is rapidly emerging at the centre stage of health care in every country. WHO is playing a major role in determination of public health policies, strategies and implementation of relevant programmes? WHO estimates\textsuperscript{337} that currently one third of the world's population lacks, access to essential drugs and that over 50 per cent of people in poor countries in Africa and Asia do not have access to even the most basic essential drugs.

\textsuperscript{336}See supra note 277 page no. 275
\textsuperscript{337}WTO Agreement and Public Health – Published by WTO Secretariat VII – 2002 (p.16)
According to WHO, access to essential medicines and vaccines depends on four critical elements?

(1) Rational selection and use;

(2) Sustainable financing;

(3) Reliable supply systems; and

(4) Affordable prices.

The Doha Declaration on the TRIPS Agreement and public health states:

“... We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all”.

The Doha Declaration on the TRIPS Agreement and public health is comprised of 7 paragraphs. The first three are preambles. The fourth paragraph includes the decision in support of member’s rights to take measures to protect public health and provide affordable access to medicines. The fifth paragraph clarifies the provision on compulsory licensing and exhaustion of IP rights.

TRIPS Agreement does not limit the grounds on which members may grant compulsory licenses, that each member has the discretion to determine the

338 ibid
existence of a public health emergency, and that the TRIPS Agreement permits each member to adopt its own policies and rules regarding the exhaustion of IP rights and parallel trade\textsuperscript{339}.

It is in October 2012, the Health Ministry of India announced its plans to ban branded drugs to curtail the rising cost of healthcare and promote healthcare affordability. Under this directive, all pharmaceutical companies are required to submit generic names in place of brands to apply for a license to manufacture Fixed Dose Combinations (FDC). Also, doctors in the public sector have been directed to prescribe generics instead of branded drugs. The amendment is part of a series of reforms, such as expanding the essential drug list from 74 to 348 in 2011, Market Based Pricing for essential drugs, and foreign direct investment in medical insurance, by the ministry.

On an average, about 86 per cent of the total healthcare expenditure in India is out-of-pocket. Out of this, nearly 72 per cent is spent on medicines (largely on branded drugs). As per industry standards, a generic drug is expected to cost between 80–85 per cent less than a branded drug. Looking at the cost difference, this move by the Indian health ministry is focused on reducing the out of pocket costs amongst consumers. While this reform is expected to increase the affordability of healthcare, it does pose challenges for the industry overall, such as quality control, implementation, and industry acceptance, which will likely impact the success of these reforms. The Indian Supreme Court on April 1, 2013 denied patent for the Novartis breakthrough drug Glivec (Imatinibmesylate). Although the case primarily focused on the concept of ever greening in Indian patent law, in the background lays the controversial issue of striking a balance between providing incentives for

\textsuperscript{339} Frederick N. Abbott., WTO TRIPS Agreement and its implications for access to medicines in developing countries, commission on intellectual property rights, study paper 2a found at http:www.iprcommission.org/graphic/documents/study_papers.htm
continued research and development and adequate access to drugs.  

A group of Ministers (GoM) has recommended revised pricing mechanism under the New Pharma Pricing Policy (NPPP) and have forwarded it for cabinet. It is well known that due to market led consumer awareness and availability, branded medicines are sold by drug manufacturers at higher prices than their unbranded generic equivalents, which are as good in therapeutic value. Therefore, if generic medicines are made more accessible and available in the market, everyone would benefit.

Accordingly, a Task Force of senior officers of the Department of Pharmaceuticals, CEOs of Pharma CPSUs, representatives of Pharma industry, NGOs/charitable organizations, State Governments, and most importantly doctors from reputed national level institutions like AIIMS, Maulana Azad Medical College and RML Hospital was constituted to implement the objective of making available affordable medicines for all. Hence looking into this opportunity government of India’s, Pharma Advisory Forum in its meeting held on 23rd April, 2008 under the Chairmanship of Shri Ram Vilas Paswan, Hon'ble Union Minister of Chemicals & Fertilizers and Steel, Decided to launch a Jan Aushadhi Campaign. A key initiative under the campaign would involve opening of Jan Aushadhi stores where, unbranded quality generic medicines would be sold which are available at lower prices, but are equivalent in potency to branded expensive drugs.

The Jan Aushadhi Campaign would ensure that

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340 Indian Supreme Court places clarity on the concept of "ever greening" of drug patents, (available at http://www.spoor.com)accessed on 27 Feb 2015, at 1.50pm


1. Make quality the hallmark of medicine availability in the country, by ensuring, access to quality medicines through the CPSU supplies and through GMP Compliant manufacturers in the private sector.

2. Despite constraints of budget in the Central and State governments, extend coverage of quality generic medicines which would reduce and thereby redefine the unit cost of treatment per person.

3. Develop a model which can be replicated not only in India but also in other less developed countries in their common goal of improving quality affordable health care by improving access to quality medicines at affordable prices for all.

4. Not be just restricted to the Public Health System but be adopted with zeal and conviction by the Private Sector and thereby spread its coverage to every village of this country. The Jan Aushadhi campaign is open for all. Since generic equivalents are available for all branded drugs, the campaign will provide access to any prescription drug or Over the Counter (OTC) drug for anybody. It will be as much available to the disadvantaged sections of the society as much to the advantaged richer population segment of the country.

5. Create awareness through education and publicity so that quality is not synonymous with high price but less is more that is to say that, with a lesser price, more medicines would be available, more patients would be treated and more people will lead a healthier life.
6. Be a public program involving State governments, the Central government, Public Sector enterprises, private Sector, NGOs, Cooperative bodies and other institutions.

7. Create a demand for generic medicines By All for all by improving access to better healthcare through low treatment costs and easy availability wherever needed in all therapeutic categories.  

Benford of the Jan Aushadhi Campaign

The Jan Aushadhi initiative will make available quality drugs at affordable prices through dedicated stores selling generic medicines which are available at lesser prices but are equivalent in quality and efficacy as expensive branded drugs. Some comparative prices are: Prices in Rs. as of (Sep, 2013)

TABLE -3

<table>
<thead>
<tr>
<th>Name of Salt</th>
<th>Dosage</th>
<th>Pack</th>
<th>Jan Aushadhi Price</th>
<th>Market Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tab. Ciprofloxacin 250mg 10</td>
<td>12.89</td>
<td>54.79</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tab. Ciprofloxacin 500mg 10</td>
<td>24.99</td>
<td>125.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tab. Diclofenac 100mg 10</td>
<td>4.20</td>
<td>60.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tab. Cetrizine 10mg 10</td>
<td>2.75</td>
<td>20.00</td>
<td></td>
<td></td>
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</tbody>
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ibid
<table>
<thead>
<tr>
<th>Name of Salt</th>
<th>Dosage</th>
<th>Pack</th>
<th>Jan Aushadhi Price</th>
<th>Market Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tab. Paracetamol</td>
<td>500mg</td>
<td>10</td>
<td>3.03</td>
<td>09.40</td>
</tr>
<tr>
<td>Tab Nimesulide</td>
<td>100mg</td>
<td>10</td>
<td>3.16</td>
<td>39.67</td>
</tr>
<tr>
<td>Cough Syrup</td>
<td>110ml</td>
<td>Liquid</td>
<td>13.30</td>
<td>33.00</td>
</tr>
</tbody>
</table>

The Jan Aushadhi Campaign will accordingly:

a) Promote greater awareness about cost effective drugs and their prescription.

b) Make available unbranded quality generic medicines at affordable prices through public-private partnership.

c) Encourage doctors, more specifically in government hospitals, to prescribe generic medicines.

d) Enable substantial savings in health care more particularly in the case of poor patients and those suffering from chronic ailments requiring long periods of drug use.

**Important Next Steps**

A list of Unbranded Generic medicines, commonly used by patients for chronic and other diseases, has been prepared. The National List of Essential Medicines, 2003 (NLEM, 2003) has also been used for this purpose. This will be considered as Common List (CL). Each State
would be able to have an add-on list called the State List (SL) based on the use of any specific medicine in the area.

The State Governments/NGOs/Charitable/cooperative/Government bodies will be encouraged to establish Jan Aushadhi stores in Government hospital premises or at other suitable location in all the Districts of all the States and union Territories. Under the Jan Aushadhi campaign Jan Aushadhi stores will be opened in all the districts in the country in phases. Accordingly, States have been identified for opening of the Jan Aushadhi stores in the first phase along with the proposed nodal organizations responsible for coordinating the activities. After successful operationalization of the program in these districts, other districts in other States would be considered in subsequent phases.

Medicine availability and prices in both public and private sectors are key indicators of access to treatment. Surveys of medicine prices and availability, conducted using a standard methodology, have shown that poor medicine availability, particularly in the public sector, is a key barrier to access to medicines. Public sector availability of generic medicines is less than 60% across WHO regions, whereas Private sector availability of generic medicines is higher than in the public sector in all regions.344

Due to low availability of medicines in the public sector, patients are often forced to purchase medicines in the private sector. For originator brand products, private sector prices were at least 10 times higher than international reference prices in all WHO regions. When originator brands are prescribed and dispensed for products that are also available in generic form, patients are paying four times more, on average, to purchase the brand.

344 See infra note 341
prices increase the cost of treatment. Additional problems of affordability face people living with chronic diseases due to the lifelong nature of treatment and the frequent need for combination therapy.

Countries should intensify efforts to measure and regularly monitor medicine prices and availability, and adopt policy measures to address the issues identified. A range of policy options are available to address issues of high prices and low availability of medicines. Low public sector availability can be addressed through improved procurement efficiency, and adequate, equitable and sustainable financing. Medicine prices can be reduced by eliminating duties and taxes on medicines and promoting the use of quality-assured generic medicines. Mark-ups can also be regulated to avoid excessive add-on costs in the supply chain. The most appropriate actions to follow depend on a country’s individual survey results and their underlying determinants, as well as local factors including existing pharmaceutical policies and market situations.345

High medicines prices, low affordability and poor availability are key impediments to access to treatment in many low- and middle-income countries (1–9). Certainly, in those countries where the majority of the population still buys its medicines through out-of-pocket payments,

Inequity in medicines access is widely perceived as symptomatic of weaknesses in the health-care system and represents a failure on the part of national governments to fulfill their obligations towards their citizens in terms of their right to health. Ensuring equitable access to quality pharmaceuticals is thus a key development challenge and an essential component of health system strengthening and primary health care reform programs throughout the world.

Health and development promotion are central components of the United Nations Millennium Project, expressed by the Eight Millennium Developmental Goals (MDG).\textsuperscript{346} The target for 2015 under this is to halt and begin to reverse the spread of dangerous diseases under MDG8, which is to ‘develop a global partnership for development’; one of the stated targets is to provide access to essential drugs in developing countries in cooperation with pharmaceutical companies.\textsuperscript{347}

The Millennium Development Goals (MDGs) acknowledge the critical importance of improving access to medicines in setting MDG target 8E, which is:

“In co-operation with pharmaceutical companies, to provide access to affordable essential drugs in developing countries”.

Improved access is also a prerequisite to the achievement of several other MDGs, namely MDG 4 (reducing child mortality), MDG 5 (improving maternal health) and MDG 6 (combating HIV/AIDS, malaria and other diseases).

According to a paper\textsuperscript{1} published by the World Health Organization (WHO), the standards stipulated in TRIPS Agreement are not necessarily appropriate for all countries' level of development. The important feature of the various new IPR regimes is for strengthening the rights of the owners of IPRs whereas their obligations have been significantly diluted. The Member countries of WTO are under obligation to enact or amend their domestic legislation for various IPRs to conform to the provisions of the TRIPS Agreement.\textsuperscript{348} In the

\textsuperscript{346} Available at http://www.UN.org/ millennium
\textsuperscript{347} For annual assessments on progress towards the millennium development goals report(published by the statistics Division of united nations department of economic and social affairs), available at http://www.un.org/millenniumgoals/reports
\textsuperscript{348} Globalization and Access to Drugs - Implication of TRIPSAgreement, A.P. Series No. 7 – November 1997
post- TRIPS period, pharmaceutical multinationals have far more freedom to operate in developing countries

The pharmaceutical industry is world’s one of the high research-intensive industries, generating enormous contributions to healthcare. Patents are granted to create strong incentives for investment in pharmaceutical research and development but that result in monopoly privileges by creating scarcity. This monopoly grant arouses public concern over high prices and the introduction of products of uncertain efficacy or safety. The pharmaceutical industry has a distinguishing characteristic of imperfect information on the quality of the product. The pharmaceutical products are often obtained on prescription from a physician. Thus, the consumer is not the decision maker. This has serious implications for prices of the pharmaceutical products as the physician is not as sensitive to prices as the direct consumer would be. The presence of monopoly power results in prices that commonly exceed drug production costs by substantial margin.

Apart from obvious implications for the consumer, such as cheaper drug options and over-the-counter accessibility, the pharmaceutical companies will face a great deal of change from the current model of the industry. The major changes will come in the research and development (R&D) sector of companies. The patent cliff in the upcoming years has implications on more than just the pharmaceutical industry.

Apart from drug discovery research and drug marketing, the current healthcare system will also face new challenges in coverage, while physicians and hospitals must provide adequate care with diminished specialty therapy. While academic institutions, hospitals, and corporations operate very differently,

each institution has the same underlying mission of improving the lives of people in need. With this mission statement in mind, the patent cliff provides an important opportunity for these health systems to collaborate and reinvent the current model of drug research, development, and distribution for the future with regard to affordability and availability of medicines in India, in the wake of amendment of patent act in 2005. 350

The Indian Supreme Court has refused to allow one of the world's leading pharmaceutical companies to patent a new version of a cancer drug, decision campaigners hailed as a major step forward in enabling poor people to access medicines in the developing world. Supreme Court has not only taken right decision but just decision also. 351

Novartis lost a six-year legal battle after the court ruled that small changes and improvements to the drug Glivec did not amount to innovation deserving of a patent. 352 The ruling opens the way for generic companies in India to manufacture and sell cheap copies of the drug in the developing world and has implications for HIV and other modern drugs too. Through this case the Supreme Court has not only upheld and allowed Indian generics manufacturersto offer Glivic for a fraction of the Novartis price, it is equally about establishing the principle that “ever greening of patents” 353 is not easy in India. This will allow India’s pharma companies to produce a wide range of drugs at low prices that can be sold to emerging countries. 354.

350See supra note299
351 See infra note 340
352 http://www.novartis.com/newsroom (accessed on 27th Feb 2015 at 1.30 pm)
353 “Evergreening of patent means making small changes to a drug, often about to come off patent in order to gain a new patent that extends its manufacturers control over it(pharma patents )
354 http://www.guardian.co.uk/world/2013/novartis denied-cancer drug patent in India
Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. But this does not mean the abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices. This goes against the spirit of the patent system and is not justified. Given the vital investments made by the public sector over decades that makes the discovery of these medicines possible.^[355]

An intellectual property regime necessarily sets up a monopoly which limits the supply alternatives for a given chemical entity to a single firm. Despite the existence of several substitutes (either because of other older molecules or due to the absence of product patents), lack of information and reliance on the physician to prescribe a drug lead to the persistence of high price for well-established pharmaceutical products.

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^[355]: Indian Supreme Court rejects trivalevergreenning of pharma patents
http://www.techdirt.com/articals/2013/se:rejects evergrenning:
Revenue of Indian pharmaceutical industry

The Indian pharmaceuticals market is expected to grow at a CAGR of 12.1 per cent to reach US$ 45 billion in 2020.
Revenue share of Indian pharmaceutical sub-segments

With 72 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector.

Export data of Indian pharma industry

In terms of value, pharmaceutical products exports have increased at a CAGR of 26.1 per cent to US$ 10.1 billion during FY06–13.

Export data of Indian pharma industry

In terms of value, pharmaceutical products exports have increased at a CAGR of 26.1 per cent to US$ 10.1 billion during FY06–13.

FIGURE -4
Indian pharmaceutical market segments by value

Anti-infective drugs command the largest share (17.8 per cent) in the Indian pharma market.

FIGURE -5

FIGURE -6

available at www.ibef.com
The above analysis provides a glimpse of the prevailing practice of the pharmaceutical industry in India. It also eloquently highlights the encouragement shown by the Government of India in helping the patients to make available the required drug at an affordable price.

Hence, government of India has come out with the entire necessary legal framework to combat implications of patent act of 2005 on pharmaceutical industries. It is promoting industries with aid for R&D funding for upgradation, reconstruction of sick public sector industries, new policies have been framed in India, make in India, mergers and acquisitions of pharmaceuticals and etc., in India, at present, pharmaceuticals are holding good position at world front also multinational drug manufacturers are expanding their activities into other areas of outsourcing activities. Drug manufacturers, because of soaring costs of research and development are moving more and more on discovery, research and clinical trial activities to the sub-continent to establish administrative centres, by capitalizing on India’s high levels of scientific expertise as well as low wages. With regard to availability and affordability of medicines, government has launched janushadi programme to see that medicines reach people in needy. Through its generic medicines outlets, it is distributing medicines, to any part of the world. Tamilnadu model of distribution should be followed by states.

Hence India should use the present patent system in a creative manner to promote technological capacity and can lead to country’s economic growth, inconsonance with concept of development, adopted at international level as human right should also be promoted and protected.

In the recent decision, (Novartis AG v/s union of India and others) supreme court of India, held that, in complying to international commitments under international treaties, “the pharmacy of the world” should also be protected.
The court has reminded its duty to uphold the rights granted by the statute but also should not put lifesaving drugs beyond the reach of the multitude of ailing humanity, not only in India but in many developing and under developed countries, depended on generic drugs from India. Even under TRIPs agreement, under article 7&8 gives scope for member countries to frame their respective national laws keeping welfare of people and development of nation in mind. In the Doha Declaration Nov.2001, also it is recognised that protection of intellectual property is important for the development of new medicines and there should be concern about its effect on prices. Finally, TRIPs agreement can and should be interpreted and implemented in a manner supportive of member’s right to protect public health and in particular to promote access to medicines for all. In India while harmonizing the patent law in the country with provisions of the TRIPs Agreement, it has strove to balance its obligations under the international treaty and its commitment to protect and promote public health considerations, not only of its own, but in many other parts of the world( more specifically the developing countries and the least developed counties).

In line with this world health assembly have also urged to use to the full, the flexibilities contained under TRIPs Agreement (WHA 56.27, May 2003 and 57.14, May 2004). In accordance with its mandate WHO will therefore seek to provide technical assistance and support to member states to promote implementation of the TRIPs agreement consistent with the public health objective of ensuring access to medicines.

As India is the leader in the global supply of affordable (generic) drugs and other essential medicines. Our Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to medicines, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines.